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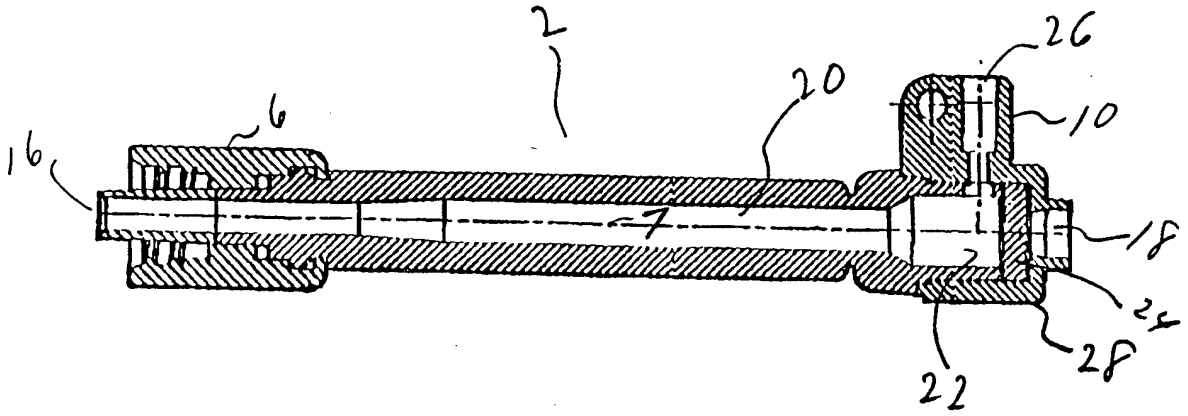

(57) Abstract

A proximal cardiovascular fitting including an elongated body with proximal and distal ends having a central passage formed therein, the central passage extending two openings at the distal and proximal ends, the opening at distal end being attachable to a proximal portion of a catheter or other tube-like device, the proximal end having a housing, the housing having a passive gasket fitted therein distally of the proximal opening, the passive gasket having apertures provided therein to receive and seal a variety of thicknesses of rod-like instruments which may be passed therethrough, whereby the fitting will maintain hemostasis in the presence as well as in the absence of such rod-like instruments passed through the passive gasket.

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PROXIMAL CARDIOVASCULAR CATHETER FITTING WITH WIDE RANGE PASSIVE SEAL

Field of the Invention

This invention relates to fittings which are attached to the proximal end of catheters used for cardiovascular and other medical procedures.

Background of the Invention

This invention relates to improvements in fittings which may be attached to the proximal end of a variety of catheters (such as guide catheters) used in coronary angioplasty and angiography or other procedures in which it is desired to seal a tubular member to prevent the escape of fluids and particularly blood. More particularly, the invention concerns the type of fitting used on the proximal end of a guide or other catheter for purposes for closing or sealing the catheter. In angioplasty and angiography procedures, a guide catheter is inserted, usually through a catheter introducer, into the arterial system of the patient undergoing the procedure. Because the guide catheter is within the arterial system of the patient, the catheter will become filled with blood from the pressure within the arterial system. This will cause a leakage of blood out of the guide catheter. It is, of course, desirable to eliminate or at least minimize blood loss to the patient, both from the standpoint of the health of the patient as well as it relates to the potential spread of blood-borne diseases to persons performing the procedure.

At present, a common apparatus for controlling such blood leakage is a so-called Tuohy-Borst fitting. A Tuohy-Borst fitting of the type shown in the Seifert et al. patent, U.S. Patent No. 5,045,061 has a main fitting attached to the proximal end of a catheter. Within the fitting is a hollow

portion containing an expandable resilient gasket. A second fitting is telescoped within the first fitting using a threaded connection. The second fitting has an open passage extending from its proximal to its distal ends in axial alignment with the axis of the catheter to which it is fitted. A catheter, such as an angioplasty catheter, or a guidewire, may be passed through the passage of the fitting and into the guide catheter. When it is desired to seal the proximal end of the catheter, the second fitting of the Tuohy-Borst fitting within the first fitting is turned so as to screw down the second fitting and move it in a distal direction using the threaded connection. This causes the resilient washer to deform itself to seal around the catheter or guidewire placed through the fitting. This action prevents the leakage of blood out of the catheter. If it is desired, however, to exchange a guidewire or a catheter, it becomes necessary to unscrew the second fitting of the Tuohy-Borst fitting so as to relieve the pressure on the gasket and thus allow removal or movement of the catheter or guidewire. A problem associated with loosening of the Tuohy-Borst fitting is that arterial blood may leak past the fitting. In addition, while the Tuohy-Borst fitting can assure complete hemostasis (lack of blood loss), the degree to which may be necessary to tighten down on the fitting may severely impair the ease of manipulating the catheter or guidewire.

Furthermore, it is desirable, if not necessary, to purge all air from the catheter to which the Tuohy-Borst fitting is attached. With Tuohy-Borst fittings presently available, the most common method used is to unscrew the fitting until all air is exhausted and only blood escapes past the resilient gasket and out of the body of the fitting. In addition, with conventional Tuohy-Borst fittings, it is difficult to take continuous blood pressure measurements during a procedure, because the fitting must be loosened in order to move or remove a catheter or guidewire positioned within the

Tuohy-Borst fitting. This action causes a loss of pressure within the catheter, making accurate pressure reading during that period unobtainable.

Another problem associated with Tuohy-Borst fittings relates to the two conflicting desires on the one hand to maintain a seal on the catheter or guidewire passing through the fitting while on the other hand there is a desire to maintain the maneuverability and "feel" of the catheter. During a procedure, the physician may advance and withdraw a catheter through the patient's system and rely on the "feel" of the catheter as it progresses through the patient's arterial system. With too tight a seal on the catheter, much, if not all of the "feel" is eliminated.

Certain prior art devices have attempted to resolve the problem of maintaining a seal using both a Tuohy-Borst seal and a passive seal as well. One example is U.S. Patent No. 4,886,507, issued to Patton et al. which discloses a combined Tuohy-Borst valve and a membrane seal. The membrane seal disclosed is utilized to seal the passage for large size catheters while the Tuohy-Borst fitting is used to seal smaller diameter catheters and guidewires. Similarly, U.S. Patent No. 4,726,374, issued to Bales et al., discloses a hemostasis valve which combines a Tuohy-Borst fitting with a passive low pressure sealing valve. As is described in Bales, a first tubular resilient gasket may be intermittently released so as to provide little or no sealing to allow manipulation of a wire member or guidewire passing through the valve while still providing low pressure sealing by the second passive gasket. The foregoing arrangements require that there be two gaskets utilized to seal catheter and guidewires, thus increasing the cost and the number of parts required for effective sealing purposes. An additional problem related to each of the Patton et al. and Bales et al. prior art patents is that in order to evacuate air from the valve or fitting, it is required that their respective screw valves be opened so that air will pass through the valves.

This, of course, is undesirable in that blood leakage past the valve could cause problems of infection for the surgeon and of other staff performing the procedure.

Other prior art devices have attempted to satisfy the need for a simple, yet effective valve in a catheter fitting. For example, U.S. Patent No. 5,098,405, issued to Peterson et al., discloses a catheter adaptor with a side port connection and a one piece integral resilient valve which serves to prevent backflow of blood from the patient. In addition, U.S. Patent No. 5,073,168, issued to Danforth, discloses a Y-adaptor which has at its distal portion a flap valve which is utilized to seal around a catheter placed through the adaptor.

Furthermore, U.S. Patent No. 4,655,752 issued to Honkanen et al. disclose a surgical cannula with a sealing member at its proximal end.

A problem associated with many of the prior art devices is their inability to provide a passive seal for a variety of catheters and guidewires of different diameters while maintaining an effective seal against blood leakage. In addition, Tuohy-Borst fittings, while effective in sealing catheters and guidewires against blood leakage, have the negative effect of decreasing the "feel" of the catheter which is desirable for the surgeon to manipulate the catheter or guidewire through the patient's vascular system.

It would be desirable, therefore, to provide a fitting in which sealing is performed through use of a passive gasket or seal usable over a wide variety of catheter and guidewire diameters while maintaining the "feel" for the physician manipulating a catheter or guidewire through the patient's arterial system. It is also desirable to provide a fitting which can be purged of air easily without risking leakage of possibly contaminated blood out of the catheter. Furthermore, it is also desirable to provide a fitting which allows continuous pressure monitoring of the patient's blood

pressure. It is among the objects of the present invention to provide such a system.

Summary of the Invention

In accordance with one aspect of the invention, a hemostasis fitting has an elongated tubular body portion, the distal end of which has a connector, such as a Luer fitting, for connection to the proximal end of a catheter (such as a guide catheter or other tubular member). The proximal end of the tubular body contains a passive gasket or seal as well as a side leg fitting distally of the gasket or seal. While the tubular portion may be constructed as a straight tube-like fitting, it may also be constructed in the form of a Y-body connector with a side arm. The side leg connection positioned distally of the gasket performs a number of functions. One function of the side leg is to allow, in a conventional manner, injection of medicines into the patient's blood system. In addition, the presence of the side leg will facilitate evacuation of any air contained within the catheter and fitting by allowing the exhaust of air through the side leg and an attached 3-way stopcock without the physician risking exposure to possibly contaminated blood.

The side leg allows for continuous pressure monitoring of the patient's blood pressure throughout a procedure. This is advantageous when compared to the Tuohy-Borst fittings of the prior art because, as explained above, there will be a pressure loss with a Tuohy-Borst fitting. In the Y-body embodiment of the present invention, the side arm of the Y-body may be used to introduce fluids such as X-ray contrast fluid through the side arm and into the bore of the catheter, a common part in angiography or angioplasty procedures.

Furthermore, with the ability of the present invention to take continuous pressure measurements within the guide catheter it is also possible to take differential pressure readings within a catheter. For example, with a balloon-type

catheter introduced through the fitting, it is possible to measure the differential between the pressure in the guide catheter with the pressure within the balloon catheter. The function or operation of the sideleg attachment is disclosed and claimed in co-pending application Serial No. 07/926,678, filed August 7, 1992, for "Proximal Catheter Fitting With Attached Sideleg".

Thus, with use of the present invention, angioplasty and angiography procedures may be facilitated by using a passive gasket which has the ability to seal a variety of catheters and guidewires. This facility allows for continuous pressure monitoring and hemostasis without the use of a Tuohy-Borst or other type of fitting which have the additional requirements of having to be manipulated to seal a catheter or guidewire.

Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof with reference to the accompanying drawings wherein:

Fig. 1 is an illustration of a straight body fitting with a passive gasket and side leg.

Fig. 2 is an enlarged cross-sectional illustration of the straight body fitting showing the passive gasket.

Fig. 3 is a side-view of a gasket which is utilized with the fitting of Fig. 1.

Fig. 4 is a end-view of the gasket of Fig. 3 viewed through the proximal entry port of the fitting of Fig. 1.

Fig. 5 illustrates another embodiment of the fitting of Fig. 1 in a Y-body configuration.

Fig. 6 illustrates a cross-sectional view of the fitting of the embodiment of Fig. 5.

Description of the Illustrative Embodiments

Fig. 1 illustrates generally a cardiovascular catheter fitting 2 with the capability of sealing, with a passive

seal, a wide range of catheters and guidewires. The fitting 2 includes a main elongated body member 4. Attached to the distal end of the body 4 is a male Luer lock fitting 6 adapted for attachment to the proximal end of a catheter having a female Luer lock connection. Of course, other types of fittings may be suitably utilized.

In certain cardiovascular procedures, a guide catheter is introduced, usually through a catheter sheath, into the vascular system of the patient on whom the procedure is to be performed. Because the guide catheter is contained within the vascular system of the patient, a reoccuring problem is that blood within the vascular system may enter the guide catheter and exit from the patient's body. Inasmuch as this is undesirable for purposes of limiting blood loss as well as for purposes of reducing the risks of contaminated blood from the patient coming into contact with the physician or other personnel performing the procedure, it is usual practice to seal the end of the guide catheter to prevent such leakage. As explained above, in prior art devices, such fittings utilize well known Tuohy-Borst fittings or variations of such fittings, which, like the fitting of the present invention, will seal the passage of the guide catheter. Tuohy-Borst fittings operate to provide hemostasis (lack of blood loss) both with a catheter or guidewire passed through the fitting as well as in the absence of the same.

Thus, in the present invention the fitting 2 is designed and constructed to replace prior art Tuohy-Borst fittings but, unlike the prior art Tuohy-Borst fittings, relies on a passive gasket to achieve hemostasis. The Luer lock fitting 6 may be fashioned to allow rotation of the fitting 2 about central axis 11. At the proximal end of the fitting 2, and proximally of the elongated tubular section 4, is a fitting 8, the purpose of which will be explained in further detail below. Also integral with the proximal fitting 8 is a side leg attachment 10 and a tube 12 leading to a standard 3-way valve 14.

Turning now to Fig. 2, Fig. 2 shows a cross-sectional view of the first embodiment of the present invention. As can be seen in reference to Fig. 2, a passage 20 runs along the central axis 7 of the fitting 2 and is open on each of its ends 16 (in the distal portion of the fitting) and 18 (in the proximal portion of the fitting 2). Contained in the proximal portion of fitting 8 shown in Fig. 2 is an additional passage 22 which may be enlarged proximally of the passage 20. A passive seal or gasket 24 is positioned within the passage 20 distally of the proximal opening 18 shown in the embodiment of Fig. 2. The passive seal or gasket 24 provides a seal against the escape of blood past the fitting 2 as well as permits the insertion of catheters and guidewires of various sizes therethrough while maintaining an effective seal. The passive seal or gasket is shown in greater detail in Fig. 3 and will be explained below. Contained in the side leg fitting 10 is a passage 26 which communicates with the passage 22. The passage 26 is positioned distally of the seal or gasket 24 for purposes which will be explained below. A tube or other flexible member 12 may be inserted into the passage 26 of fitting 10 as shown in Fig. 1. A 3-way or other suitable valve, such as a 2-way valve or a 4-way valve may be attached to the proximal portion of the tube 12. The side leg fitting 10 and side leg passage 26 perform several functions in the embodiment of Figs. 1 and 2. The first purpose of the side leg fitting 10 with its attendant tubing 12 connected to 3-way stopcock 14 is to allow the purge of any air contained within the guide catheter or other catheter to which the fitting 2 is attached.

In addition, even if the guide catheter to which the fitting 2 is attached has been purged of air, there must be some means for purging the air contained within the tubular passages 20 and 22 within the fitting. In prior art Tuohy-Borst fittings, air is purged from the system by unscrewing the Tuohy-Borst valve to allow the resilient

gasket to release its seal, allowing air to escape from the fitting. The physician will screw down the Tuohy-Borst fitting to reestablish the seal once blood is seen to escape from the proximal end of the fitting. This, of course, has disadvantages, including the escape of possibly contaminated blood which may be dangerous to the physician and other persons present for the medical procedure. The present invention, however, prevents such blood loss while effectively permitting purge of air from the system.

In the operation of the embodiment of the present invention, the fitting 2 is first attached to the proximal end of a guide catheter by means of a Luer lock fitting 6. The guidewire catheter may contain a corresponding Luer lock fitting. If it is desired to purge any air in the guide catheter and passage 20, 3-way stopcock 14 is opened, a conventional valve contained within the stopcock 14. This opening allows air to pass through passage 26, then through tube 12, and then through to fitting 15 in the 3-way stopcock. Fitting 15 may itself be attached to a wastebag to contain any blood which may inadvertently have escaped from passage 12. As can be seen by reference to Fig. 2, the passage 26 is positioned just distally of the seal or gasket 24, thus permitting maximum removal of any air from the system.

An additional feature provided by the side leg housing 10 of the present invention is that constant pressure monitoring during a coronary procedure can be performed. In practice, a pressure gauge would be attached to one of the legs of the 3-way valve 14, such as leg opening 17, and the 3-way valve oriented to allow flow of blood to the pressure gauge. With this arrangement, it is possible to constantly monitor the blood pressure of the patient throughout the procedure, even during catheters or guidewires removal or exchange. With the prior art Tuohy-Borst type of fitting, it is necessary to unscrew the fitting to allow the resilient gasket to release its pressure seal around the catheter or guidewire being

removed or exchanged. In doing so, there will be loss of pressure within the system which is undesirable for the physician who may be interested in monitoring constant pressure measurements. The seal or gasket 24 of the present invention is passive and does not require (or allow) any manipulation during catheter or guidewire removal or exchange. Thus, pressure monitoring can be constant.

A further use of the side leg fitting 10 in passage 26 is the use of the fitting in connection with dilatation of a stenosis or lesion within the patient's arterial system using a balloon catheter . As discussed previously, a constant pressure monitoring of the patient's blood pressure can be accomplished using a pressure gauge attached to a side leg of the 3-way stopcock 14. This pressure reading would thus represent the blood pressure of the patient's arterial system. In a balloon catheter dilatation procedure, a balloon catheter is inserted into a patient's arterial system and is positioned distally of a stenosis. Such dilatation catheter may have attached to its proximal portion a pressure transducer. This pressure transducer will produce a reading of the pressure in the vicinity of the stenosis within the patient's arterial system during an angioplasty procedure. In the conventional manner of use, the balloon at the distal end of a balloon catheter will be alternatively inflated and deflated in order to push back the plaque which comprises the material of the stenosis. Prior to the first inflation of the balloon catheter, there will be a pressure differential between the pressure measured of the patient's blood pressure, as measured by the blood transducer attached to the fitting of the present invention, and the blood pressure sensed by the transducer which is fixed distally of the stenosis. Upon successive inflations and deflations of the balloon the stenosis will be substantially reduced in size, thus opening up the arterial passage. At the time when the stenosis has been opened to its fullest extent, the pressure reading differential will become minimal thus indicating that

a stenosis has been substantially reduced and the arterial passage substantially opened.

Turning now to Fig. 3, that figure illustrates one form of a gasket which may be used in conjunction with the fitting of the embodiment shown in Figs. 1 and 2. The passive gasket may be embodied in a variety of different forms. For example, the gasket shown and disclosed in U.S. Patent No. 4,424,833, issued January 10, 1988, to Spector et al. may be utilized. However, in the preferred embodiment, the gasket shown in Fig. 3 is preferred. As shown in Fig. 3, the gasket 24 is shown in cross-sectional form. The end drawing of Fig. 4 shows the gasket to be of a circular configuration but other configurations may be suitably used as desired by the design of the cross-sectional shape of the passage 22 into which the gasket is fitted. In Fig. 4, it is seen that the gasket 24 is placed and held within the passage 22 by an end cap 28. Fitting 28 may be attached to the main body 2 through suitable means such as heat shrinking or welding or gluing. As shown in Fig. 2, the proximal side 30 of gasket 24 communicates with passage 18. Passage 18 is sized to allow the passage through of catheters and guidewires and other instruments therethrough to communicate with the passage 20 of the fitting 2.

In the gasket of Fig. 3, one side 30 of the gasket 24 has a central hole 32 formed therein. The central aperture or hole 32 is dimensioned to be approximately 0.012" through approximately 0.024" in diameter preferably in steps of .004", that is, .012", .016", .020" and .024". Most catheters and guidewires in use today exceed those diameters and thus the diameter of the central hole 32 allows the gasket body to form a seal around a gasket or around a catheter. The central hole is also preferably of a depth into the gasket of .020" (for a gasket of approximately .046" overall thickness). Catheters vary in diameter and guidewires vary in diameter as well, depending on the purpose for which they are used and on the physiology of the

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patient. The material of the gasket or seal may preferably be made of a Dow silicon material such as material number Q74720, manufactured by Dow Chemical Co. of a durometer of 35-40 Shore A. The thickness of the seal or gasket 24, shown as dimension 32 in Fig. 3, may range from 0.046" to 0.070" dependent upon the size of the catheters and guidewires a particular fitting is designed to seal against. The diameter 33 of the gasket may be preferably approximately .311", although this may be varied dependent on the size of the housing in which the gasket is fitted. The opposing face of the gasket 24 illustrated in Fig. 4 as side 34, contains a number of slits 36 cut into the face 36 and passing preferably through the gasket body to at least meet with the opening formed by the hole 32 formed in the side 30 of the gasket 24. The number of slits used is shown as numbering 3 in Fig. 4 as slits 38, 40 and 42, but may be any number of slits as desired or as suitable depending upon the application.

The length of the slits may be any length as suitable. The gasket of the present invention is generally similar in form to the gasket described in co-pending application Serial No. 07/817,941 filed January 2, 1992, and entitled "Self-Sealing Guidewire and Catheter Introducer" and assigned to the assignee of the present invention. The radially extending slits 38, 40 and 42, on the inner face of the gasket 30 may extend radially a distance that is slightly greater than the maximum diameter of catheter with which the device is to be used.

Thus, applicants have provided a novel proximal cardiovascular catheter fitting which provides for sealing over the large variety of catheters and guidewires which may be introduced into a guide catheter while using a simple passive gasket which additionally has the advantages disclosed above, including the ability to maintain pressure monitoring throughout an entire procedure.

Turning now to Figs. 5 and 6, Fig. 5 shows another embodiment of the proximal fitting of Figs. 1 and 2 with the addition of an additional side arm. As shown in Fig. 5, Y-body 50 includes a central passage 52 and a side passage 56. As can be seen in Fig. 6, the Y-body fitting 50 has a central portion 52 which has an elongated passage or bore 56 passing through the length of the body 52 and having a central axis 58. The inclined side arm 54 has an opening 60, a central passage or bore 62, and a central axis 64 which meets the axis 58 of the main bore 52 at 66. The function of the Y-body side arm is well known in the art, and includes among its purposes the introduction of contrast fluids through the fitting and into the guide catheter for the well known purposes of angiography and angioplasty. In all other aspects, the embodiments of Figs. 5 and 6 are identical to the functions disclosed above with reference to Figs. 1, 2, and 3 of the first embodiment including the gasket or seal utilized.

The system described herein is not intended to be limited to a fitting which is attachable only to the proximal ends of guide catheters. The fitting is useful in any setting the user desires to maintain hemostasis. Furthermore, it is not necessary that the fitting be separately detachable from the proximal end of a catheter and it considered within the scope of the present invention to construct the fitting as an integral part attached to the proximal end of the catheter or in a form in which the fitting may be attached by means other that a Luer-type lock to the catheter.

Examples would include welding or gluing or heat shrinking of the fitting to a catheter. The proximal fitting with passive seal described herein combines the advantages of simplicity and of construction in that the separate parts contained within a Tuohy-Borst fitting are not required with the construction of the present invention. In addition, the present invention provides advantages over prior art Tuohy-Borst fittings in that the "feel" is maintained over

the variety of catheters and guidewires of variant diameters without having to make any adjustments. Furthermore, catheter movement is not impaired during a angiography or angioplasty procedure in that it is not required that the Tuohy-Borst fitting be unscrewed to relieve pressure on the resilient gasket so that the catheter may be moved or exchanged for another catheter or a guidewire.

As mentioned earlier, the ability to provide a passive seal around catheters and guidewires as well as a seal even without the presence of any catheter or guidewire, which allows the operator to constantly monitor pressure within the patient's blood system, and which eliminates the need for use of the physician's hand to turn a Tuohy-Borst fitting, are facilities which are not obtainable with prior art Tuohy-Borst fittings.

Therefore, applicants have disclosed herein a novel proximal cardiovascular catheter fitting which accommodates to seal a wide variety of different size catheters and guidewires while additionally allowing for the advantages of facilitating purging of air from the system, preventing constant pressure monitoring of the patient's blood system, as well as the ability to measure pressure differentials between the patient's arterial system and the pressure within a stenosis when utilizing the present invention in conjunction with a balloon dilatation catheter.

In addition, any specified materials of construction or dimensions disclosed are not intended to be limiting, rather thus, otherwise provided, the fitting and its gasket may be constructed of any material commonly used and appropriate to the art. It should be understood, however, as the foregoing description of the invention is intended to be merely illustrative thereof and that other modifications and embodiments may be apparent for those skilled in the art without departing from its spirit. Having thus described the invention, what we desire to claim and secure by Letters Patent is:

Claims

1. A proximal cardiovascular fitting comprising:

an elongated body with proximal and distal ends having a central passage formed therein, the central passage extending to openings at the distal and proximal ends, the opening at the distal end being attachable to a proximal portion of a catheter or other tubelike device, the proximal end having a housing, the housing having a passive gasket fitted therein distally of the proximal opening, the passive gasket having apertures provided therein to receive and seal a variety of thicknesses of rod-like instruments which may be passed therethrough, whereby the fitting will maintain hemostasis in the presence as well as in the absence of such rod-like instruments passed through the passive gasket.

2. The proximal catheter fitting of claim 1 further comprising a Luer type lock attached to the distal portion of the fitting, whereby the lock may be attached to proximal portions of catheters with matching Luer lock fittings.

3. The proximal catheter fitting of claim 1 wherein the rod-like instruments comprise catheters and guidewires.

4. A proximal catheter fitting of claim 1 further comprising a side arm formed on the elongated body, the side arm having a passage, the distal end being in communication with the central passage of the elongated body at its distal end, the proximal end of the passage of the side arm being open and adapted for connection to a syringe for purposes of introducing contrast or other fluid, through the proximal catheter fitting.

5. A proximal cardiovascular fitting comprising:

an elongated body with proximal and distal ends having a central passage formed therein, the central passage extending to openings at the distal and proximal ends, the opening at distal end being attachable to a proximal portion of a catheter or other tubelike device, the proximal end having a housing, the housing having a passive gasket fitted therein distally of the proximal opening, the passive gasket being a self-sealing one piece gasket mounted in the housing and being exposed at the opening at the proximal end, the gasket having a central aperture in its outwardly facing surface, the aperture depth being substantially equal to one-half the thickness of the gasket, the inwardly facing surface of the gasket being formed with at least three radially extending slits, the depth of the slits being equal to or greater than one-half of the thickness of the gasket, the central region of the slits overlapping the central aperture and defining a plurality of flaps normally closing the aperture, the gasket being adapted to receive a guidewire or a catheter extended therethrough.

6. The proximal cardiovascular fitting of claim 5 wherein the thickness of the gasket is in the range of .046" to .070".

7. The proximal cardiovascular fitting of claim 5 wherein the gasket is formed from a molded elastomeric material having a Shore A diameter of 35-40A.

8. The proximal cardiovascular fitting of claim 5 wherein the central aperture is in the range of .012" to .024" in diameter.

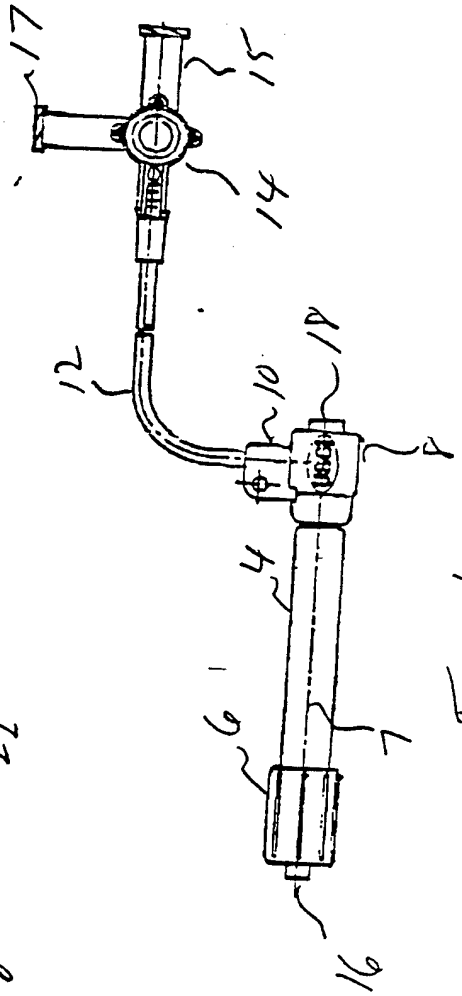

Fig. 1

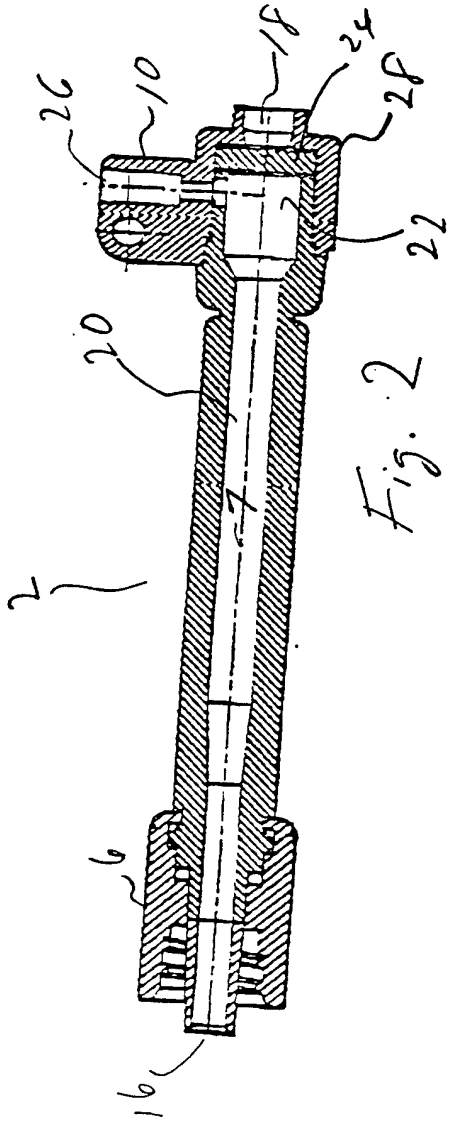

Fig. 2

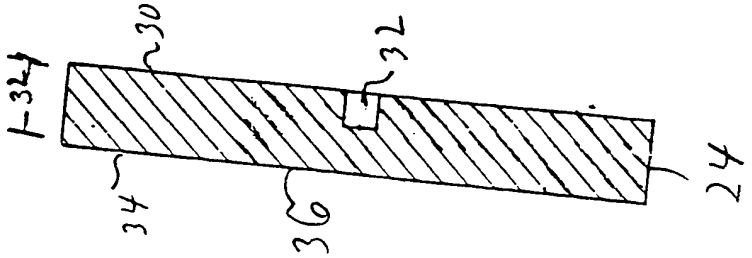

Fig. 3

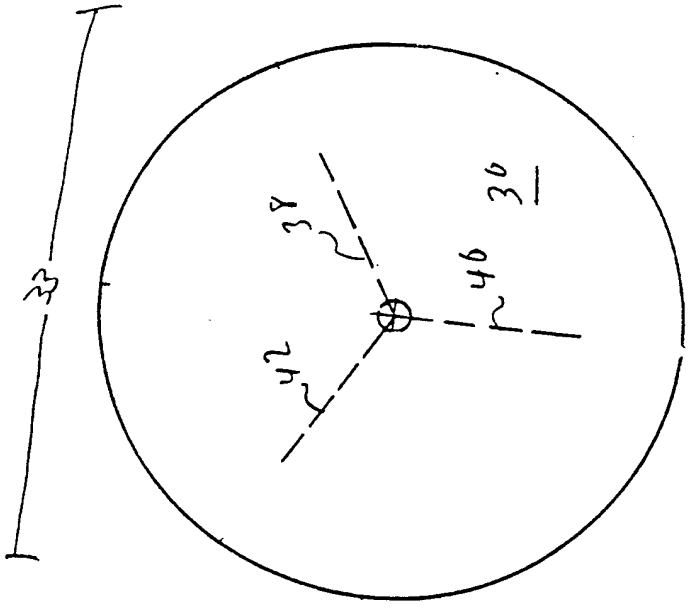

Fig. 4

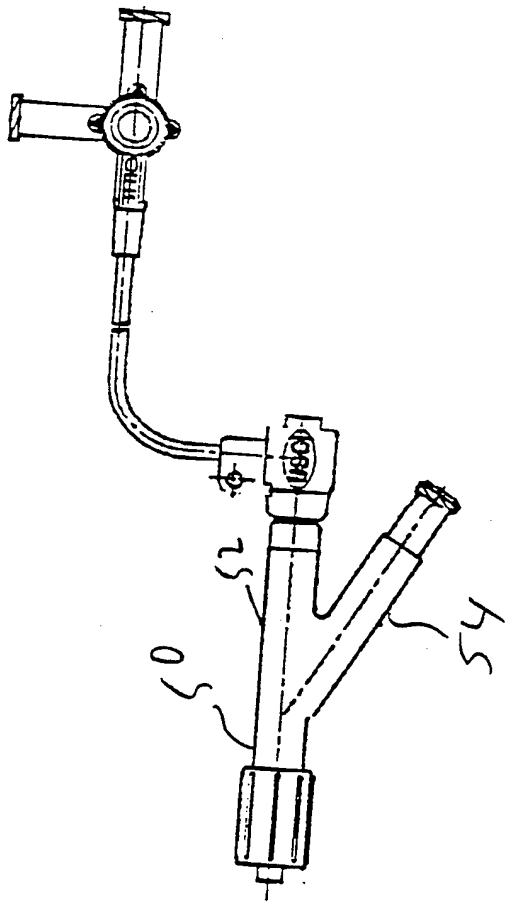

Fig. 5

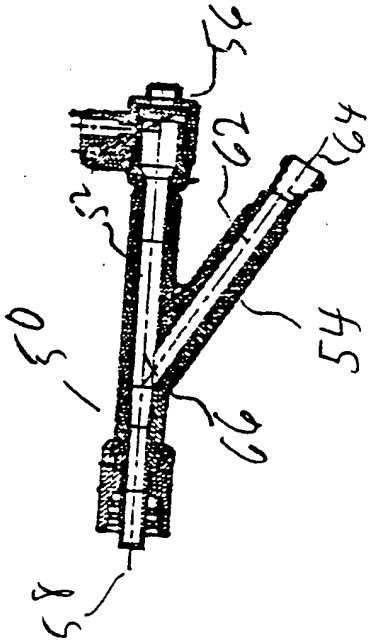

Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 93/07271

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M39/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	EP,A,0 344 907 (BARD) 6 December 1989 see the whole document	1,3-7
Y	---	2
Y	US,A,4 857 062 (RUSSELL) 15 August 1989 see abstract; figure 2	2

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20 OCTOBER 1993	
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	KOUSOURETAS I.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9307271
SA 77470

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 20/10/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0344907	06-12-89	AU-B- 621359	12-03-92
		AU-A- 3475589	21-12-89
		JP-A- 2029267	31-01-90
US-A-4857062	15-08-89	None	